4. PROGRAM REGULATIONS

409.401: Introduction

The regulations in 130 CMR 409.000 state the requirements for the purchase, rental, and repair of durable medical equipment (DME), and for the purchase of medical/surgical supplies under MassHealth. All durable medical equipment and medical/surgical supplies must be of proven quality and dependability, and must conform to all applicable federal and state product standards.

409.402: Definitions

The following terms used in 130 CMR 409.000 have the meanings given in 130 CMR 409.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 409.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 409.000, and in 130 CMR 450.000.

Accessory Equipment — products that are fabricated primarily and customarily to modify or enhance the usefulness or functional capability of another piece of equipment and that are generally not useful in the absence of that other piece of equipment.

Adjusted Acquisition Cost —
(1) except where the manufacturer is the provider, the price paid by the provider to the manufacturer or any other supplier for DME, customized equipment, or medical/surgical supplies, excluding all associated costs such as, but not limited to, shipping, handling, and insurance costs; and
(2) where the manufacturer is the provider, the actual cost of manufacturing such DME or supplies.

Customized Equipment — DME that is made-to-order or adapted to meet the specific needs of a particular patient and that is sufficiently specialized or modified to preclude the use of such equipment by subsequent patients.

(1) Custom Fabricated — the equipment in question has been made for the patient from measurement and/or patterns only.

(a) Molded to Patient Model — a plaster cast of the involved portion of the patient's body from which a positive cast is then developed. This positive mold represents the patient model from which the ultimate equipment is fabricated.

(b) Non-molded — no casting or molding techniques used in the fabrication of the equipment in question. The equipment can be a stock item or can be made from measurement and/or patterns only.

(2) Custom Fitted — no casting or molding techniques in the fabrication of the equipment in question.

Durable Medical Equipment — products that:

(1) are fabricated primarily and customarily to fulfill a medical purpose;
(2) are generally not useful in the absence of illness or injury;
(3) can withstand repeated use over an extended period; and
(4) are appropriate for home use.

Eligible Provider — any person, partnership, corporation, or other entity authorized by the Division to engage in the business of furnishing DME, medical/surgical supplies, or customized equipment, and who meets such conditions of participation as may be adopted by a government unit.

Emergency Service — a serious situation, such as a medical crisis, that arises suddenly and threatens the life or welfare of a person.

Licensed Physician — a physician licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

Medical/Surgical Supplies — medical/treatment products that:

(1) are fabricated primarily and customarily to fulfill a medical or surgical purpose;
(2) are used in the treatment of a specific medical condition;
(3) are generally not useful in the absence of illness or injury; and
(4) are non-reusable and disposable.

Mobility System — any manual or motorized wheelchair or other wheeled device, such as a scooter, including its components, accessories, and modifications, that is prescribed by a physician.

Personal Emergency Response System (PERS) — an electronic device hooked to a person's telephone line. In an emergency, it can be activated either by pushing a small button on a pendant, pressing the help button on the console unit, or by an adaptive switch set-up. When the device is activated, a person from the 24-hour-a-day, seven-day-a week central monitoring station answers the call, speaks to the patient via the console unit, assesses the need for help, and takes appropriate action. A medical communication system qualifies as a PERS if it includes all four of the following requirements:

(1) an in-home medical communications transceiver;
(2) a remote, portable activator;
(3) a central monitoring station with backup systems staffed by trained attendants 24 hours a day, seven days a week; and
(4) current data files at the central monitoring station containing preestablished response protocols and personal, medical, and emergency information for each client.

Seating and Mobility (or Wheelchair) Clinic — a clinic held at a facility such as a hospital or rehabilitation center where the rehabilitation technology supplier and the member meet with a physician and physical or occupational therapist, each of whom has expertise in equipment provision, to determine and prescribe the most appropriate seating and/or mobility system or wheelchair to meet the medical needs of the member.

Seating System — a seated positioning system, including its components, accessories, and modifications, designed to meet the individualized needs of a member.

Service Facility — a DME business or branch of a DME business where services, especially repairs or replacements, can be obtained, and that is accessible to MassHealth members.

Special Adaptive Mobility System — a wheelchair or a scooter that is of the type classified as K0004 through K0014 or E1230 in Subchapter 6 of the *Durable Medical Equipment Manual* and that is for the personal full-time use of a member residing in a nursing facility.

Special Adaptive Mobility System Add-On — a part that is of the type classified as K0015 through K0109 in Subchapter 6 of the *Durable Medical Equipment Manual* that may be added on to a base wheelchair and that is for the personal full-time use of a member residing in a nursing facility.

409.403: Eligible Members

(A) MassHealth Members. The Division covers DME services provided to eligible MassHealth members, subject to the restrictions and limitations described in the Division's regulations. The Division's regulations at 130 CMR 450.105 describe the services covered and the members eligible under each coverage type.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

409.404: Provider Eligibility

Payment for services described in 130 CMR 409.000 will be made only to providers of DME, DME repair services, or medical supplies who are participating in MassHealth as of the date of service. In addition, the following eligibility requirements must be met.

(A) In State.
(1) A provider located in Massachusetts must primarily engage in the business of providing DME, DME repair services, or medical supplies to the public and meet all state and local requirements for engaging in such a business.
(2) A provider of DME, DME repair services, or medical supplies must have a service facility, as defined at 130 CMR 409.402 in the Commonwealth of Massachusetts.

(B) Out of State. A provider located outside of Massachusetts is eligible to participate in the MassHealth DME program only if he or she:
(1) participates in the medical assistance program (or the equivalent) of the state in which the provider primarily conducts business;
(2) primarily engages in the business of providing DME, DME repair services, or medical supplies to the public and meets all of their state and local requirements for engaging in such a business; and
(3) has a service facility as described in 130 CMR 409.402, within 50 miles of the Massachusetts border.

409.405: Durable Medical Equipment, Repair Services, and Medical Supplies Provided by Eligible Out-of-State Providers

In accordance with 42 CFR 431.52(b), the Division covers services furnished in another state by a provider as described at 130 CMR 409.404(B) to the same extent that it would cover services within its boundaries by a provider as described at 130 CMR 409.404(A) if the services are furnished to a member who is a resident of Massachusetts. However, if the provider's service facility is beyond the 50-mile limit described in 130 CMR 409.404(B)(3), the Division will pay for services only where one of the following conditions is met:

(A) services are needed because of a medical emergency as described in 130 CMR 409.402;

(B) medical services are needed and the member's health would be endangered if he or she were required to travel to his or her state of residence;

(C) the Division determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other state; or

(D) it is general practice for members in a particular locality to use medical resources in another state.

409.406: Nonreimbursable Services

(A) The Division does not pay for DME or medical/surgical supplies that are experimental in nature, unless the provider has obtained prior authorization from the Division.

(B) The Division does not pay for nonmedical equipment or supplies. Equipment that is used primarily and customarily for a nonmedical purpose is not considered medical equipment, even if such equipment has a medically related use. Medical equipment and supplies must meet the requirements set forth in 130 CMR 409.402.

(C) The Division does not pay for DME or medical/surgical supplies that are not, in its determination, both necessary and reasonable for the treatment of a member's medical condition. This includes, but is not limited to:

(1) items that cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness or injury;
(2) items that are substantially more costly than medically appropriate and feasible alternative pieces of equipment; or
(3) items that serve the same purpose as those items already in use by the member.

(D) The Division does not pay for accessory equipment unless the item for which the equipment is an accessory is reimbursable under these regulations. If the item for which the accessory equipment is required was not purchased by the Division, the Division may request a physician's prescription, pursuant to 130 CMR 409.407, to justify the need for the item.

(E) The Division does not pay for the repair of any equipment unless such equipment is reimbursable under these regulations.

(F) The Division does not pay for routine periodic testing, cleaning, regulating, and checking of equipment. This limitation does not apply to extensive maintenance that, based on the manufacturer's recommendations, must be performed by authorized technicians. Such extensive maintenance is considered a repair service and is reimbursable under 130 CMR 409.425.

(G) The Division does not pay a DME provider for the evaluation or diagnostic test used to establish the medical need for durable medical equipment or associated supplies.

409.407: Prescription Requirements

(A) The rental or purchase of DME and the purchase of medical/surgical supplies are reimbursable only after the provider has obtained a written prescription signed by a licensed physician or nurse practitioner. The prescription must be dated within 90 days of the requested date of service (which is the initial date of service requested in the prior authorization request), or within 90 days of the date the prior-authorization request is received by the Division if prior authorization is required, whichever is longer. The prescription must contain the following information:

(1) the member's name and address;
(2) specific identification of the prescribed item;
(3) medical necessity criteria for the use of the item (including the diagnosis and disabling condition);
(4) the estimated length of time that the item will be used by the member;
(5) the location in which the member will customarily use the item;
(6) the prescriber's address and telephone number; and
(7) the date on which the prescription was signed by the prescriber.

(B) The prescription must be written on the prescriber's prescription pad, the prescriber's letterhead stationery, or a Region A Durable Medical Equipment Regional Carrier (DMERC) certificate of medical necessity. If the Region A DMERC certificate of medical necessity is used, it must be completed in accordance with the instructions established by the Region A DMERC, in addition to complying with these regulations.

(C) The provider must keep the physician's prescription on file for a minimum of four years following the date of service.

409.408 Prior Authorization

(A) The provider must obtain prior authorization as a prerequisite for payment for DME, medical/surgical supplies, or services listed in 130 CMR 409.409 and 409.410, except as specified in 130 CMR 409.431(B). Prior authorization does not waive any other prerequisites for payment including, but not limited to, requirements relating to member eligibility or resort to health insurance payment.

(B) All prior-authorization requests must be submitted in accordance with the instructions in Subchapter 5 of the *Durable Medical Equipment Manual*. Before determining the medical necessity of an item for which prior authorization is requested, the Division may, at its discretion, require an evaluation by a registered physical therapist or another health-care professional who has expertise in equipment provision, to determine whether the requested item will meet stated medical and functional needs, given the member's physical condition and the physical environment in which the item will be used.

(C) An invoice that reflects the provider's adjusted acquisition costs according to regulations found at 130 CMR 409.420 must be included with the prior-authorization request for each item.

(D) Manufacturers who provide services must submit documentation that demonstrates, to the Division's satisfaction, the cost of manufacturing the item provided, as described in 130 CMR 409.420(D).

(E) The provider must submit the request for prior authorization within 90 days of the requested date of service (date of delivery) or within 90 days after the prescription is generated. Failure to submit the request within the 90-day period will result in a denial of payment.

(F) Written notification of the prior-authorization decision will be sent to the member and the provider, and will indicate approval, modification, or denial. Deferrals will be sent back to the provider with a reason for the deferral and an opportunity to resubmit. The provider is responsible for explaining the deferral reason to the member. Notification of denial will include the reason for the denial. The provider has the right to resubmit additional information, as does the member or the prescriber, through the provider. The member may appeal the denial of a prior-authorization request within 30 days after the date of the notice of denial. Procedures for such an appeal are set forth in 130 CMR 610.000.

(G) The Division will take no longer than 15 days after the date of receipt to decide on a prior-authorization request. The Division will confirm the date of receipt and the date of the decision upon written request. If, after 15 days, the Division is notified that it has not yet acted on a prior-authorization request, the Division will so act within 24 hours of receiving such notice. When, in the event of an emergency medical need, the 15-day period to act would jeopardize the member's health, a prior-authorization request may be made by telephone to the Division's Prior Authorization Unit. If authorization is granted, a prior-authorization number will be given by telephone, and a written follow-up will be sent upon receipt of the required documentation from the provider.

409.409: Purchases Requiring Prior Authorization

(A) The purchase of any of the following equipment requires prior authorization:
(1) manual or electric hospital-bed systems;
(2) hospital-bed accessories, including mattresses;
(3) standard transport devices, including patient lifts;
(4) manual or electric mobility systems, including wheelchairs;
(5) decubitus-care apparatus, including alternating pressure pads and pumps;
(6) all items listed in Subchapter 6 of the *Durable Medical Equipment Manual* that are indicated as needing prior authorization ("P.A."); and
(7) all items that are not listed in Subchapter 6 of the *Durable Medical Equipment Manual* whose price totals more than $25.00.

(B) The provider must inform the Division when the requested item is to replace equipment currently rented or previously purchased by the Division.

409.410: Rentals Requiring Prior Authorization

The rental of any of the following requires prior authorization:

(A) manual hospital bed systems listed as rental equipment in Subchapter 6 of the *Durable Medical Equipment Manual*;

(B) electric hospital bed systems;

(C) standard transport devices, including patient lifts;

(D) manual mobility systems, including wheelchairs, listed as rental equipment in Subchapter 6 of the *Durable Medical Equipment Manual*, after a rental period of three months;

(E) electric mobility systems, including wheelchairs;

(F) personal emergency response systems (PERS) as defined in 130 CMR 409.402 (see Subchapter 6 of the *Durable Medical Equipment Manual*); and

(G) all equipment that is not listed as rental equipment in the DME list in Subchapter 6 of the *Durable Medical Equipment Manual.*

(130 CMR 409.411 through 409.419 Reserved)

409.420: Adjusted Acquisition Cost

Adjusted acquisition cost is defined in 130 CMR 409.402.

(A) For purposes of 130 CMR 409.000, the term "discount" means any remuneration or reduction of payment of any kind, whether direct or indirect, actually realized by the provider. Any provider who fails to disclose and pass on any such discounts to the Division may be subject to civil and criminal penalties, including imprisonment, in accordance with state and federal laws M.G.L. c. 118E, s. 41, and 42 U.S.C. sec. 1320a-7b(b)(3)(A).

(B) Except where the manufacturer is the provider, the adjusted acquisition cost must not exceed the manufacturer's current wholesale price, and must be evidenced by the purchase price of the equipment listed on a copy of the supplier's invoice. Where the manufacturer is the provider, the adjusted acquisition cost must not exceed the actual cost of manufacturing the item(s). Those manufacturing costs may include only the cost of raw materials, labor, and overhead.

(C) If the equipment has not been purchased by the provider at the time of the prior-authorization request, a quote reflecting the absolute lowest price of the item may be substituted for the receipted invoice. The quotation must be on the manufacturer's letterhead or form and must be addressed to the provider.

(D) Where the manufacturer is the provider of any item covered under 130 CMR 409.000, the manufacturer must submit documentation that demonstrates to the Division's satisfaction the actual cost of manufacturing the item, as set forth in 130 CMR 409.420(B).

(E) The actual receipted invoice must be placed in the member's records. This record must be maintained and available to the Division pursuant to 130 CMR 409.434 and 450.205.

409.421: Purchase of Durable Medical Equipment and Medical/Surgical Supplies (Excluding Customized Equipment)

(A) Payment to a provider for the purchase of DME and medical/surgical supplies is the lowest of:
(1) the provider's usual and customary charge to the general public;
(2) the adjusted acquisition cost of the item plus a markup not to exceed:

(a) 50 percent for any item whose adjusted acquisition cost is less than $25.00;
(b) 45 percent for any item whose adjusted acquisition cost is $25.00 or greater and less than $100.00;
(c) 40 percent for any item whose adjusted acquisition cost is $100.00 or greater and less than $200.000;
(d) 35 percent for any item whose adjusted acquisition cost is $200.00 or greater and less than $300.000; or
(e) 30 percent for any item whose adjusted acquisition cost is $300.00 or greater; and

(3) the fee set forth in the schedule of maximum allowable fees that may be adopted by the Division as an amendment to these regulations.

(B) Payment for the following is included in the fee calculated in accordance with 130 CMR 409.421(A):

(1) all accessories required to complete the initial set-up;
(2) delivery of equipment to the inside of the member's residence and, when appropriate, to the room in which the equipment will be used;
(3) installation and/or set-up of the equipment;
(4) instruction of the member in the safe use of the equipment;
(5) removal of the equipment; and
(6) necessary adjustments to the completed equipment for six months after the initial date of service.

(C) DME and medical/surgical supplies that are retail-stock items must be:

(1) clean (sterilized when appropriate);
(2) in proper working condition;
(3) free from defects; and
(4) new and unused at the time of purchase, except for redeemed equipment.

(D) When a member ceases to need DME purchased for the member by the Division, the member or the member's estate must promptly notify the provider. The provider must recover such equipment to determine if it is redeemable under 130 CMR 409.421(D)(2). Recovery of such equipment is mandatory for the first three years after purchase, but optional thereafter.

(1) The Division will send an equipment-recovery notice to the provider with the approved prior-authorization form for purchased equipment. The provider in turn must deliver such notice to the member when the provider delivers equipment that the Division has purchased.
(2) If the equipment is redeemable, the provider must send a check, payable to the Commonwealth of Massachusetts, to the Division of Medical Assistance. Redeemable equipment is defined as equipment that:

(a) is no longer needed by the member;
(b) has a current adjusted acquisition cost, as defined at 130 CMR 409.402, of more than $400.00 and has been purchased by the Division within the last three years; and
(c) the provider determines upon inspection to be resaleable or returnable to the provider's inventory, after appropriate reconditioning.

(3) For redeemable equipment, the amount remitted to the Division must conform to the following redemption schedule:
(a) within one year from the date of purchase—30 percent of current adjusted acquisition cost;
(b) within two years from the date of purchase—20 percent of the current adjusted acquisition cost; and
(c) within three years from the date of purchase—15 percent of the current adjusted acquisition cost.

(4) If the provider determines that the equipment is not redeemable, the provider must send a letter to the Division's Delivery Systems Unit within 30 days after the equipment is recovered, stating that the equipment is not redeemable. The letter must include the provider's name, the member identification number, the type of equipment, the date of the determination, and a brief statement of the reason the equipment is not redeemable.

409.422: Purchase of Customized Durable Medical Equipment, Special Adaptive Mobility Systems, and Special Adaptive Mobility System Add-Ons

(A) (1) Payment to a provider for the purchase of customized DME is the lower of:
(a) the provider's usual and customary charge to the general public; or
(b) the fee determined by individual consideration (see 130 CMR 409.426).

(2) Payment to a provider for the purchase of special mobility systems and special adaptive mobility system add-ons is the lower of:
(a) the provider's usual and customary charge to the general public less the first $500, which is the responsibility of the nursing facility as provided for in 130 CMR 456.414; or
(b) the fee determined by individual consideration (see 130 CMR 409.426) less the first $500, which is the responsibility of the nursing facility as provided for in 130 CMR 456.414.

(B) Payment for the following is included in the fee calculated in accordance with 130 CMR 409.422(A):
(1) all accessories required to complete the initial set-up;
(2) delivery of the equipment to the inside of the member's residence and, when appropriate, to the room in which the equipment will be used;
(3) installation and/or set-up of the equipment;
(4) instruction of the member and/or caregiver in the safe use of the equipment;
(5) customized fitting; and
(6) removal of equipment.

(C) Customized DME, special adaptive mobility systems, and special adaptive mobility system add-ons must be:

(1) clean (sterilized when appropriate);
(2) in proper working condition;
(3) free from defects; and
(4) new and unused at the time of purchase, except for redeemed equipment.

(D) When required by the Division, the provider must furnish positive evidence that the medical needs of the member could not be met with retail-stock equipment at a lower cost.

(E) When a MassHealth member ceases to need DME, special adaptive mobility systems, and special adaptive mobility system add-ons purchased by the Division, the member, the skilled nursing facility where the member resides, or the member's estate must notify the provider. The provider must recover such equipment to determine if it is redeemable under 130 CMR 409.422(E)(2). Recovery of such equipment is mandatory for the first three years after purchase, but optional thereafter.

(1) The Division will send an equipment-recovery notice to the provider with the approved prior-authorization form for purchased equipment. The provider in turn must deliver such notice to the member when the provider delivers equipment that the Division has purchased.
(2) If the equipment is determined to be redeemable by the provider, the provider must send a check, payable to the Commonwealth of Massachusetts. Redeemable equipment is defined as equipment that:
    (a) is no longer needed by the member;
    (b) has a current adjusted acquisition cost, as defined at 130 CMR 409.402, of more than $400.00 and has been purchased by the Division within the last three years; and
    (c) the provider determines upon inspection to be resalable or returnable to the provider's inventory, after appropriate reconditioning.
(3) For redeemable equipment, the amount remitted to the Division must conform to the following redemption schedule:
    (a) within one year from the date of purchase—30 percent of current adjusted acquisition cost;
    (b) within two years from the date of purchase—20 percent of current acquisition cost;
    (c) within three years from the date of purchase—15 percent of current adjusted acquisition cost.
(4) If the provider determines that the equipment is not redeemable, the provider must send a letter to the Division's Delivery Services Unit within 30 days after the equipment is recovered, stating that the equipment is not redeemable. The letter must include the provider's name, the member identification number, the type of equipment, the date of the determination, and a brief statement of the reason the equipment is not redeemable.

(F) The Division will pay for a replacement of a member's current mobility system only when:
(1) the cost of repairing the current mobility system will exceed the value of the current system; or
(2) the member's condition has changed enough to render the current mobility system ineffective.

409.423: Rental of Durable Medical Equipment

(A) The monthly rental payment for DME is the lowest of:
(1) one-sixth of the adjusted acquisition cost of the equipment for the first six months and one-twelfth of the adjusted acquisition cost of the equipment for each month after the first six months;
(2) the provider's usual and customary rental rate and terms to the general public;
(3) the fee set forth in the schedule of maximum allowable fees that may be adopted by the Division as an amendment to these regulations; or
(4) the fee determined by individual consideration (see 130 CMR 409.426).

(B) Payment for the following is included in the fee calculated in accordance with 130 CMR 409.423(A):
(1) the cost of maintenance, service, and repair of the equipment as needed, including replacement of defective parts;
(2) the cost of all accessory equipment and disposable items necessary for the proper functioning and use of the rented equipment;
(3) delivery of equipment to the inside of the member's residence and, when appropriate, to the room in which he equipment will be used;
(4) installation and/or set-up of the equipment; and
(5) instruction of the member and/or caregiver in the safe use of the equipment.

(C) DME that is rented on a monthly basis must be:
(1) clean (sterilized when appropriate); and
(2) in proper working condition.

409.424: Purchase of Rental Durable Medical Equipment

The Division at its discretion may purchase at the following rates of payment DME that is being provided on a monthly rental basis to a member.

(A) If the Division exercises the option to purchase the equipment within three months from the date of delivery of the equipment, 70 percent of the total rental payments will be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 409.421(A).

(B) If the Division exercises the option to purchase the equipment any time after three months from the date of delivery of the equipment, 70 percent of the first three monthly rental payments and 50 percent of all subsequent monthly rental payments will be applied toward the maximum allowable purchase price computed in accordance with 130 CMR 409.421(A).

409.425: Repair Services for Durable Medical Equipment

(A) All repair services are priced on an individual-consideration basis as described in 130 CMR 409.426.

(B) Whenever a repair service for purchased DME requires removing the equipment from the residential setting, the provider must supply, on a rental basis, properly working substitute equipment comparable in all respects to the equipment to be serviced. The daily rental fee is one-thirtieth of the monthly rental fee calculated in accordance with 130 CMR 409.423(B). No payment for the rental substitute equipment is made for any day following the fifth business day after the date of removal of the equipment from the residence, unless the provider obtains prior authorization from the Division.

(C) Whenever a repair service for rented DME requires removing the equipment from the residential setting, the provider must supply properly working substitute equipment comparable in all respects to the equipment to be serviced. No extra rental charge is allowed for this substitute equipment.

(D) Repairs involving three or more hours of labor are manually reviewed. Manual review requires specific documentation from the provider, including

(1) a complete description of the needed repair, including parts;
(2) the adjusted acquisition cost of the items as described in 130 CMR 409.420(B) and (C); and
(3) the actual number of hours required to complete the repairs.

(E) When a repair is required more than once in a three-month period (excluding wheelchair tires and brakes), payment will be made only if the following documentation is submitted with the claim:

(1) an invoice for the repaired or replaced item;
(2) a detailed description of the circumstances that made the second repair necessary; and
(3) an explanation as to why the repaired or replaced item is not covered under warranty.

(F) The provider of repair services is responsible for the quality of workmanship and parts, and for ensuring that repaired equipment is in proper working condition.

(G) The provider is responsible for taking advantage of all manufacturer warranties and for honoring Wheelchair Lemon Law (M.G.L. c. 93, s. 107) criteria before submitting claims to the Division for repairs to DME.

(H) Repairs that will cost more than $300 for customized mobility systems or for special adaptive mobility systems that are used as backup for a primary mobility system or special adaptive mobility system are reimbursed only after the provider has obtained prior authorization from the Division's Prior Authorization Unit as described in 130 CMR 409.408(A).

(1) The Division pays for repairs to backup customized mobility systems and specialized adaptive mobility systems when both the member's primary and backup mobility systems are so customized that no rental equipment would be comparable.

(2) Documentation describing the extent of the customization of the member's mobility systems must be submitted with the request for repair of the backup system.

409.426: Individual Consideration

Individual consideration means that the rate of payment for the purchase, rental, or repair of certain DME or for the purchase of certain medical/surgical supplies has not been established by the Division of Health Care Finance and Policy. Such items are identified in Subchapter 6 of the *Durable Medical Equipment Manual* by the designation "(I.C.)" next to the description of the item or service. The rate of payment for an item or service identified as individual consideration is determined by the Division based on the provider's descriptive report of the services provided and the adjusted acquisition cost of materials as defined in 130 CMR 409.420. If necessary, the Division, at its discretion, will submit the service for medical review.

(130 CMR 409.427 through 409.430 Reserved)

409.431: Medicare Coverage

(A) When a Medicare-covered DME service is furnished to a member who receives Medicare Part B benefits, the Division will always pay up to the Medicare reasonable cost or the Medicaid fee-for-service amount, whichever is lower. The Division's payment for such services is limited to the coinsurance and the deductible amounts. Claims for services furnished to members with Medicare benefits must be submitted in accordance with the instructions in Subchapter 5 of the *Durable Medical Equipment Manual*.

(B) Prior authorization from the Division is not required for Medicare-covered services furnished to members who receive Medicare Part B benefits.

(C) If the service that is denied by Medicare normally requires prior authorization from the Division, then the provider is required to obtain prior authorization from the Division before requesting payment from the Division. The provider may request prior authorization from the Division before submitting the claim to Medicare.

409.432: Provider Responsibility

(A) The provider is responsible for making reasonably certain that the DME or medical/surgical supplies furnished are the most cost effective, given the medical need for which they are prescribed and the member's physical limitations.

(B) Before purchasing equipment or supplies, the provider must make a reasonable effort to purchase the item from the least-costly reliable source by comparing prices charged by different suppliers for comparable items.

409.433: Durable Medical Equipment Furnished to Institutionalized Members

(A) Institutions Licensed as Nursing Facilities

(1) The Division will pay a DME provider for the purchase or repair of customized DME furnished for the personal full-time use of a member residing in a nursing facility only if the customization precludes the use of the equipment by subsequent patients in that institution, as determined by the Division.

(2) The Division will pay a DME provider for the purchase of a special adaptive mobility system in accordance with 130 CMR 409.422(A)(2).

(3) The Division will pay a DME provider for the repair of special adaptive mobility systems.

(4) The Division will not pay a DME provider for the purchase, rental, or repair for noncustomized DME or for any mobility system of the type classified as K0001 through K0003 in Subchapter 6 of the *Durable Medical Equipment Manual*, but will pay a DME provider for the purchase or repair of a special adaptive mobility system add-on to such a mobility system.

(5) The Division will not pay for medical/surgical supplies that are furnished to a member residing in a nursing facility.

(B) Institutions Licensed as Hospitals, Chronic Hospitals, or Rehabilitation Hospitals. The Division will not pay a DME provider for the purchase, rental, or repair of DME, nor for medical/surgical supplies furnished to a hospitalized member, except for DME that is prescribed primarily for the home use of a member after discharge. The member's discharge plan and date must be documented prior to the purchase, rental, or repair of the prescribed item.

(C) Institutions Certified and Licensed as Intermediate Care Facilities for the Mentally Retarded (ICF/MR) with 16 or More Beds.

(1) The Division will pay a DME provider for the purchase or repair of customized DME furnished for the personal full-time use of a member residing in a state school only if the Division determines that the customization precludes the use of the equipment by subsequent patients in that institution.

(2) The Division will not pay a DME provider for the purchase, rental, or repair of noncustomized DME, nor for medical/surgical supplies furnished to a member residing in a state school.

(D) Rest Home.

(1) The Division will pay a DME provider for the purchase or repair of DME furnished to a member residing in a rest home, subject to the conditions and limitations set forth in 130 CMR 409.000.

(2) The Division will pay a DME provider for medical/surgical supplies furnished to a member residing in a rest home.

409.434: Recordkeeping Requirements

The provider must keep a record of all DME, repair services, and medical/surgical supplies furnished to a member for at least four years following the date of service. This record must include the following:

(A) a physician's prescription for all rentals and purchases;

(B) a copy of the approved prior-authorization request for all equipment, supplies, or services requiring prior authorization;

(C) an acknowledgment of receipt, signed by the member or the member's representative, of prescribed equipment or supplies, that includes:

(1) the date of receipt of equipment or supplies;

(2) the condition of the equipment or supplies (for example, whether it is in proper working order, damaged, etc.);

(3) the manufacturer, brand name, model number, and serial number of the equipment or supplies;

(4) whether the item was purchased or rented by the Division;

(5) for repair services, a complete description of the service, including the manufacturer, brand name, model number, and serial number of the repaired item; and

(6) next to the signature, an explanation of the representative's relationship to the member by the individual acknowledging receipt. This individual cannot be associated with either the provider or the delivery service.

(a) For routine delivery of supplies, the member must acknowledge receipt at least once monthly.

(b) A signature stamp may be used by or on behalf of a MassHealth member whose disability inhibits the member's ability to write. A signature stamp may be used only by the member or the member's representative, provided that the stamp is used by the member in his or her normal course of conducting business. A signature stamp cannot be used by anyone associated with either the provider or the delivery service;

(D) an invoice showing the cost to the provider of the materials (if the provider is not the manufacturer of the materials);

(E) documentation demonstrating the cost of manufacturing the item provided (if the provider is the manufacturer); and

(F) copies of written warranties.

(130 CMR 409.435 through 409.439 Reserved)

409.440: Medical Necessity Criteria

The following requirements must be met before the Division will approve a service for reimbursement.

(A) For services requiring prior authorization, the provider must submit with the prior-authorization request documentation showing that the medical necessity criteria, set forth in 130 CMR 409.440 through 409.446, have been met.

(B) For services that do not require prior authorization, the provider must keep the documentation of medical necessity with the member's records.

409.441: Pressure Reducing Support Surfaces: Group One

(A) Definition of Service. Group-one pressure-reducing support surfaces are:
(1) nonpowered pressure-reducing mattress overlays designed to be placed on top of a standard hospital or home mattress;
(2) nonpowered pressure-reducing mattresses; or
(3) powered pressure-reducing mattress overlay systems (alternating pressure or low airloss).

(B) Requirements for Coverage.
(1) The member must meet the criterion listed in 130 CMR 409.441(B)(2)(a); or
(2) The member must meet the criteria listed in 130 CMR 409.441(B)(2)(b) or (c) and at least one of the criteria listed in 130 CMR 409.441(B)(2)(d) through (g).
(a) complete immobility (i.e., patient cannot change body position without assistance);
(b) limited mobility (i.e., patient cannot independently change body position significantly enough to alleviate pressure;
(c) any-stage pressure ulcer on the trunk or pelvis;
(d) impaired nutritional status;
(e) fecal or urinary incontinence;
(f) altered sensory perception; or
(g) compromised circulatory status.

(C) Related Clinical Information. Patients needing pressure-reducing support surfaces must have a care plan that has been established or authorized by the patient's physician. This care plan must be documented in the patient's medical records and must include the following:

(1) education of the patient and caregiver about the prevention and/or management of pressure ulcers;
(2) regular assessment by a nurse or physician;
(3) appropriate turning and positioning;
(4) appropriate wound care (for a stage II, III, or IV ulcer);
(5) appropriate management of moisture/incontinence; and
(6) nutritional assessment and intervention consistent with overall plan of care.

(D) Reasons for Noncoverage. When the medical necessity criteria set forth in 130 CMR 409.441(B) for a group-one overlay or mattress are not met, coverage will be denied as not medically necessary unless there is documentation otherwise justifying the medical necessity for the item in the individual case. The Division will determine if the documentation presented satisfies the requirement of medical necessity.

(E) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription pursuant to 130 CMR 409.407;
(2) a prior-authorization request pursuant to 130 CMR 409.408; and
(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.441(B)(2).

409.442: Pressure-Reducing Support Surfaces: Group Two

(A) Definition of Device. Group-two pressure-reducing support surfaces are:

(1) powered pressure-reducing mattress (alternating pressure or low airloss);
(2) semi-electric or total electric hospital bed with fully integrated powered pressure-reducing mattress; or
(3) nonpowered, self-adjusting pressure-relief system.

(B) Requirements for Coverage.

(1) The member must meet one of the following criteria.

(a) The member must meet the criteria listed in 130 CMR 409.442(B)(1)(c)(i), (ii), and (iii); or

(b) The member must meet the criterion listed in 130 CMR 409.442(B)(1)(c)(iv); or

(c) The member must meet the criteria listed in 130 CMR 409.442(B)(1)(c)(v) and (vi).

(i) multiple stage-II pressure ulcers located on the trunk or pelvis;

(ii) participation in a comprehensive ulcer treatment program for at least the past month that has included the use of an appropriate group-one support surface or an appropriate group-three support surface for a healing wound;

(iii) ulcers that have worsened or remained the same over the past month;

(iv) large or multiple stage-III or -IV pressure ulcer on trunk or pelvis;

(v) recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days); or

(vi) needing a group-two or -three support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days).

(2) Comprehensive ulcer treatment as described in 130 CMR 409.442(B)(1)(c)(ii) above includes:

(a) education of the patient and caregiver on the prevention and management of ulcers;

(b) regular assessment by a nurse or physician (usually at least weekly for a patient with a stage-III or -IV ulcer);

(c) appropriate turning and positioning;

(d) appropriate wound care (for a stage-II, -III, or -IV ulcer);

(e) appropriate management of moisture/incontinence; and

(f) nutritional assessment and intervention consistent with the overall plan of care.

(C) Reasons for Noncoverage.

(1) When the medical necessity criteria set forth in 130 CMR 409.442(B) for a group-two overlay or mattress are not met, coverage will be denied as not medically necessary unless there is documentation otherwise justifying the medical necessity for the item in the individual case. The Division will determine if the documentation presented satisfies the requirement of medical necessity.

(2) Continued use of a group-two support surface is covered until the ulcer has healed or, if healing does not continue, there is documentation in the medical record to show that:

(a) other aspects of the care plan are being modified to promote healing; or

(b) the use of the group-two support surface is medically necessary for wound management.

(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription pursuant to 130 CMR 409.407;
(2) a prior-authorization request pursuant to 130 CMR 409.408; and
(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.442(B).

409.443: Pressure Reducing Support Surfaces: Group Three

(A) Definition of Service. Group-three pressure-reducing support surfaces are air-fluidized beds. These are devices employing the circulation of filtered air through silicone-coated ceramic beads, creating the characteristics of fluid.

(B) Requirements for Coverage. The Division will pay for an air-fluidized bed only if all of the following criteria are met:

(1) The patient has a stage-III (full-thickness tissue loss) or stage-IV (deep-tissue destruction) pressure sore.
(2) The patient is bedridden or chair bound as a result of severely limited mobility.
(3) The air-fluidized bed is ordered in writing by the patient's physician based upon a comprehensive assessment and evaluation of the patient after conservative treatment has been attempted. Conservative treatment includes:
    (a) education of the patient and caregiver on the prevention and/or management of pressure ulcers;
    (b) assessment by a physician or nurse at least weekly;
    (c) appropriate turning and positioning;
    (c) use of a group-two support surface, if appropriate;
    (e) appropriate wound care;
    (f) appropriate management of moisture and incontinence; and
    (g) nutritional assessment and intervention consistent with the overall plan of care.
(4) The patient must have been on the conservative treatment program for at least one month prior to the use of the air-fluidized bed with worsening or no improvement of the ulcer. The evaluation must be performed within a week prior to initiation of therapy with the air-fluidized bed.
(5) A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems.
(6) A physician directs the treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed monthly if deemed necessary.
(7) All other alternative equipment has been considered and ruled out by the physician.

(C) Reasons for Noncoverage. An air-fluidized bed will be denied as not medically necessary under any of the following circumstances.

(1) The patient has coexisting pulmonary disease (lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions).

(2) The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material.

(3) The care giver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed.

(4) Structural support is inadequate to support the weight of the air-fluidized bed system.

(5) Electrical system is insufficient for the anticipated increase in energy consumption.

(6) Other known contraindications exist.

(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription pursuant to 130 CMR 409.407;

(2) a prior-authorization request pursuant to 130 CMR 409.408; and

(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.443(B).

409.444: Augmentative and Alternative Communications Devices (AAC)

(A) Definition of Service. Electronic, nonelectronic, or microprocessor-controlled aids, devices, or systems that help a member overcome or ameliorate the communication limitations that preclude or interfere with meaningful communication of messages. Examples include, but are not limited to:

(1) communication boards or books;

(2) electrolarynxes;

(3) speech amplifiers; and

(4) electronic devices that produce speech or written output.

(B) Requirements for Coverage. AAC devices are covered for members with significant expressive communication impairments if they meet the requirement found at 130 CMR 409.444 (B), (C), and (D). These impairments include the following conditions:

(1) apraxia of speech;

(2) dysarthria; and

(3) cognitive communication disabilities.

(C) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription pursuant to 130 CMR 409.407;

(2) a prior-authorization request pursuant to 130 CMR 409.408; and

(3) documentation of the patient's medical condition, pursuant to 130 CMR 409.444(B). Medical necessity may be established by the following:

(a) a diagnosis of a significant expressive communication impairment or disability;

(b) physician documentation that the impairment or disability has permanently caused communication limitations that preclude or interfere with the member's meaningful participation in current and projected daily activities; and

(c) an assessment of the member's condition and a treatment plan, both performed by a licensed speech/language pathologist independent of the provider.

(i) The treatment plan must describe the specific components of the AAC devices and the required amount, duration, and scope of the AAC services; and

(ii) documentation must demonstrate that the requested AAC device and the AAC services constitute the least costly form of treatment that will have the comparable effect of overcoming or ameliorating communication limitations that preclude or interfere with the beneficiary's meaningful participation in current and projected daily activities.

(D) Trial Period.

(1) A trial-use period of not more than two months will be authorized by the Division to determine if the device requested is appropriate for the member.

(2) The provider must obtain and submit the following documentation in order to receive a trial period with an AAC device:

(a) a prescription pursuant to 130 CMR 409.407;

(b) a prior-authorization request pursuant to 409.408;

(c) an explanation of the type of AAC device to be used by the member, including all necessary components;

(c) identification of the clinicians or therapists who will assess the trial period; and

(d) the evaluation criteria specific to the member, that will be used by the clinician or therapist to determine the success or failure of the trial period.

(3) Success of the trial period will be determined by:

(a) an evaluation by a licensed speech/language pathologist experienced in the assessment of AAC services and who is independent of the provider; or

(b) a 15-20 minute video of the member using the AAC device.

(4) After evaluating all appropriate documentation, the Division will decide whether to purchase the equipment.

(E) Reasons for Noncoverage. The Division will deny coverage of an AAC device where it determines that:

(1) the criteria set forth in 130 CMR 409.444(C) have not been met; or

(2) after a trial period, the member has failed to demonstrate to the Division's satisfaction that the device is both useful and beneficial.

409.445: Personal Emergency Response System (PERS)

(A) Requirements for Coverage.

(1) PERS is indicated for patients with conditions that cause multiple functional limitations, such as those that cause difficulties with endurance and ambulation and that contribute to a homebound status.

(2) In addition to the requirements in 130 CMR 409.445(B)(1), the member must:

(a) be physically able to summon help with the PERS unit;

(b) be mentally alert and self directing;

(c) have a functioning telephone with a direct line;

(d) be alone for extended periods or have no regular contacts;

(e) be at risk of requiring institutional services at least at the nursing facility level, as determined by the Division; and

(f) be at risk for falls or other medical emergencies.

(B) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription that is in compliance with 130 CMR 409.407;

(2) a prior authorization that is in compliance with 130 CMR 409.408; and

(3) documentation by the physician of a preexisting history that includes acute exacerbations leading to emergent or urgent care.

(C) Reasons for Noncoverage.

(1) A PERS unit is considered a duplication of services and is not covered when the patient already has equipment to meet emergency needs (e.g., TTY service, emergency call buttons, personal care attendants).

(2) The Division does not cover a PERS unit for conditions that do not characteristically cause acute incapacitation of the member unless the physician documents a preexisting history of acute exacerbations leading to emergency care requirements.

(D) Replacement. Replacements for loss or damage beyond repair are covered by the manufacturer's warranty.

409.446: Enteral Nutrition

(A) Definition of Service. Enteral nutrition is defined as supplementation with energy- and protein-rich foods for patients on modified consistency diets, the chronically ill with anorexia, and those with chronic inflammatory and malignant disease, using commercially available products that will provide intensive protein and calorie support, when the integrity of the gastrointestinal tract is preserved.

(B) Requirements for Coverage. Home enteral nutrition is reimbursable in members with a functional gastrointestinal tract who are unable to consume their diet by mouth and have a compromised nutritional status requiring supplementation.

(C) Reasons for Noncoverage. The Division will not cover home enteral nutrition for members who are underweight but have the ability to meet their nutritional needs orally.

(D) Documentation Required. The following documentation is needed for the Division to determine medical necessity:

(1) a written prescription that is in compliance with 130 CMR 409.407;
(2) a prior-authorization request that is in compliance with 130 CMR 409.408; and
(3) documentation by the physician stating the above prerequisites for instituting the above therapy.

REGULATORY AUTHORITY

130 CMR 409.000: M.G.L. c. 18, s. 10; M.G.L. c. 118E, s. 4.